

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 09/894,550</p>	<p>Applicant(s) COLLINSON ET AL.</p>	
	<p>Examiner CHERIE M. WOODWARD</p>	<p>Art Unit 1647</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 November 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 09 November 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: 4 and 12-30.
- Claim(s) objected to: _____.
- Claim(s) rejected: 96-104.
- Claim(s) withdrawn from consideration: 5-8, 11 and 32-88.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Manjunath N. Rao, /
Supervisory Patent Examiner, Art Unit 1647

Continuation of 3. NOTE: Applicant's after-final amendment amends claims 96 and 97 by adding that the "dual specificity antibody is not a fully mouse antibody." Applicant points to support at pp. 29-30 of the specification. However, these pages in the specification only provide a general definition of an antibody. The specification does positively recite a "fully mouse antibody" at p. 26, lines 25-26, but this is the only place it does so. While Applicant's amendments are not new matter under MPEP 2173.05(i) or *In re Johnson*, 195 USPQ 187, 196 (CCPA 1977), they do not overcome the art of record, which is a rejection under 35 USC 103, citing Luger, Schmidt, and Berg. Further, the after-final amendment cannot be entered because it raises new issues of indefiniteness that will need to be considered, including the degree to which an antibody is not a "fully mouse antibody". It is unclear whether changing a single CDR or whether differential glycosylation is sufficient to make an antibody not a "fully mouse antibody." Applicant has not shown whether or how their antibodies differ, if at all, from those of the prior art, which function in a manner identical to the claims - as dual specificity antibodies. Applicant argues that the antibodies of Schmidt would not bind IL-1a and IL-1b. Applicant argues that the examiner's statements are speculation. Applicant argues that there is no motivation, modification, or reasonable expectation of success of combining the three art references. Applicant argues that the antibodies of the art were not prepared by the same processes as the instant antibodies. Applicant's arguments have been fully considered, but they are not persuasive. With regard to the argument of Applicant's representative that the antibodies produced by the art are not produced by the same process as the instantly claimed antibodies (Remarks at p. 16), Applicant's representative is arguing a point not at issue. The process by which the antibodies are prepared is the subject of a method claim, not a product claim. Claims 96-104 are product claims, drawn to the antibodies themselves and not to the method by which they are made. Claims 96-104 are drawn to antibodies that are structurally and functionally characterized by what they bind to - in this case, both IL-1a and IL-1b. Thus, any antibody in the art "capable of binding" (to use the precise wording of claims 96 and 97) to IL-1a and IL-1b would meet the limitations of the claims. With respect to the argument of Applicant's representative that there is no motivation or reasonable expectation of success, and with regard to Applicant's argument that the examiner's statements are speculation, the Examiner has set forth a detailed discussion of motivation, reasoning, and predictability in the Office Actions of 5/9/2005, 8/17/2006 and 5/11/2007 (Remarks pp. 13 and 14). Further, the examiner has provided both direct support from the prior art references themselves and she has also provided exemplary references to support her reasoned statements (see, i.e. Harlow et al., Eds). It is also noted that Berg et al., is taught for the purpose of demonstrating the well known ability to make human monoclonal antibodies or to humanize antibodies, and not as Applicant's representative suggests in her remarks at p. 14, first full paragraph. Applicant is encouraged to review page 5 of the Office Action of 8/17/2006. The examiner previously stated that the rejection was amenable to evidence. However, no evidence of any kind has been submitted by Applicant demonstrating or suggesting that the antibodies of the art are not capable of binding IL-1a and IL-1b. Applicant's arguments submitted in the after-final amendment have been fully addressed. The claim amendments will not be entered because they raise new issues that would require further consideration and they are not deemed to place the application in better form for appeal by reducing or simplifying the issues for appeal.